Feasibility of a Virtual Clinical Trial that Includes Assessment and Treatment of Persons with Aphasia

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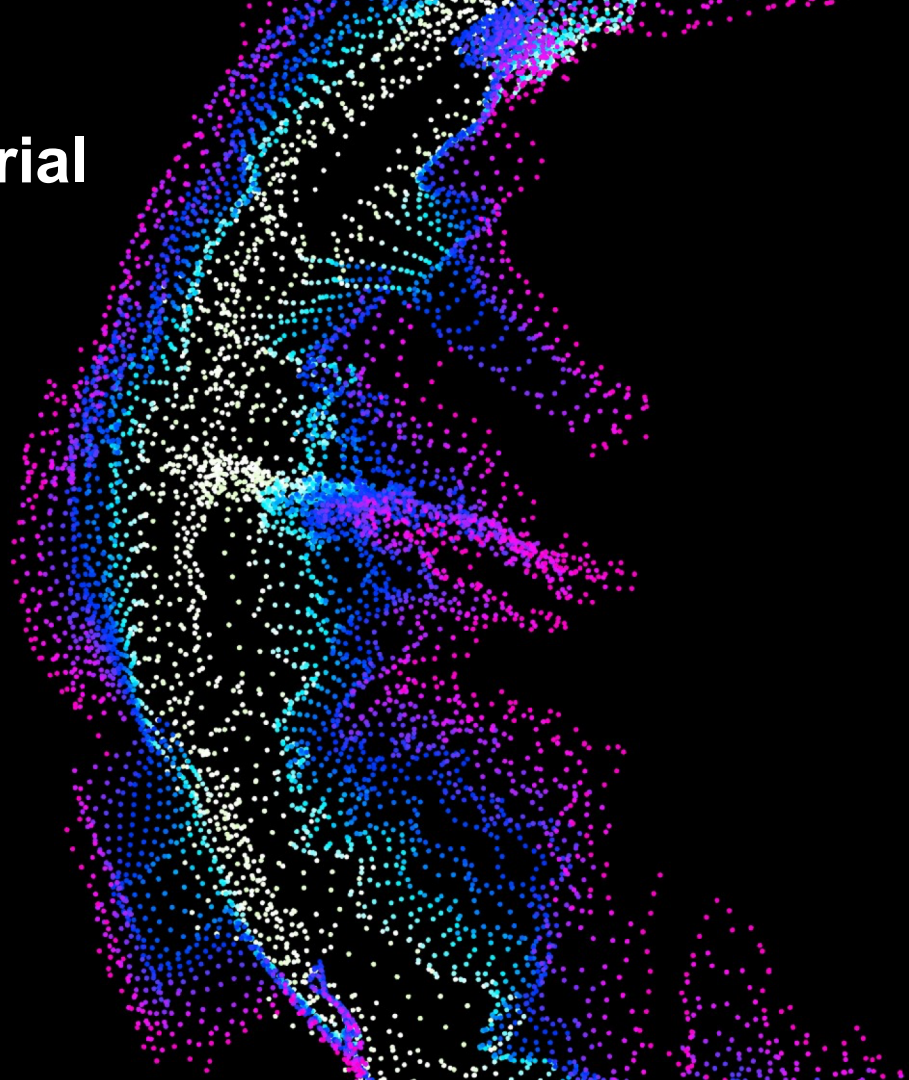
The Learning Corp



Speaker Disclosures

Michelle Braley

- Financial: Michelle is an employee of The Learning Corp, the makers of Constant Therapy
- Non Financial: Michelle has no relevant non financial relationships

Emily Dubas De Oliveira

- Financial: Emily is an employee of The Learning Corp, the makers of Constant Therapy
- Non Financial: Emily has no relevant non financial relationships

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- Financial: Co-founder and Scientific Consultant for The Learning Corp, the makers of Constant Therapy
- Non financial: Swathi has no relevant non financial relationships

Today's Agenda

- Decentralized (Virtual) Clinical Trials
- Overview of The Learning Corp's Virtual Trial
- Summary / Conclusion
- Questions

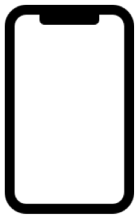
Decentralized Clinical Trials:

What are they?

Key Definitions

Decentralized Clinical Trials (DCT), also known as Virtual Trials

DCTs are conducted in a study participant's home using digital tools. They offer a way to make better informed decisions about the efficacy of new therapies (Coravos, 2018)



Contract Research Organizations (CRO)

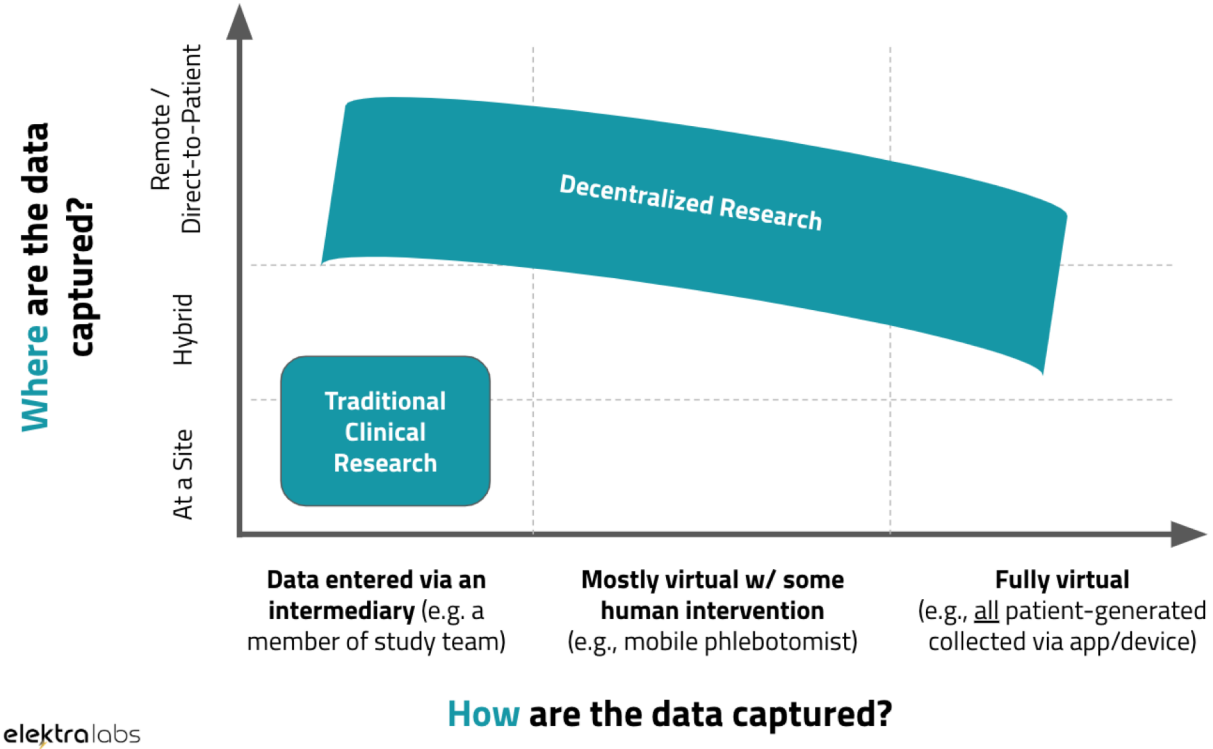
An organization that is contracted by another company to manage and lead the company's trials, duties, and functions

Endpoints

An event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial (NIH)

Traditional, Mixed Model, and Decentralized Approaches...

Decentralized studies have two components: decreased reliance (1) on an intermediary and (2) on a physical location



(Coravos, 2018)

History of Virtual Trials *(Dolgin, 2018)*

Eli Lilly - 2001

- First major pharma-backed foray into internet-based trials
- Participants filled out online questionnaires and also completed in-person visits at clinical sites

Pfizer - 2011

- First truly virtual study
  - Web-based informed consent and data collection
- 2 Key Findings:
  - Marketing was a challenge, because it was decoupled from treating physicians
  - Rigid protocol did not put interests of the participants first

Potential Concerns - *Data privacy*

"Online recruitment based on information acquired through non-transparent practices also threatens individuals privacy rights, the well-being of participants, the integrity of the trial process and ultimately the health of the public"

(Dolgin, 2018)

(Getty images)

Potential Concerns - *Reduction in MD/Specialist visits*

Industry will also have to allay fears that reduction in doctor's visits may jeopardize patient safety.

- Minimally anticipated risk
- Collective intelligence (used in tandem with SLP intervention)

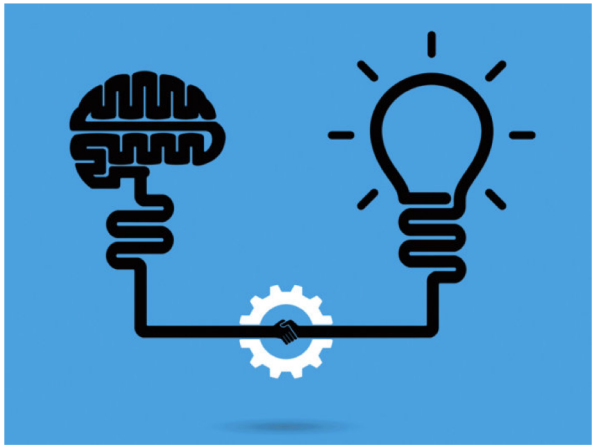
Decentralized Clinical Trials:

Why do they matter and how can we maximize their potential?

Why should we innovate?

Virtual Trials have the potential to act as a medium platform to address the common issues that have faced traditional clinical trial approaches, such as:

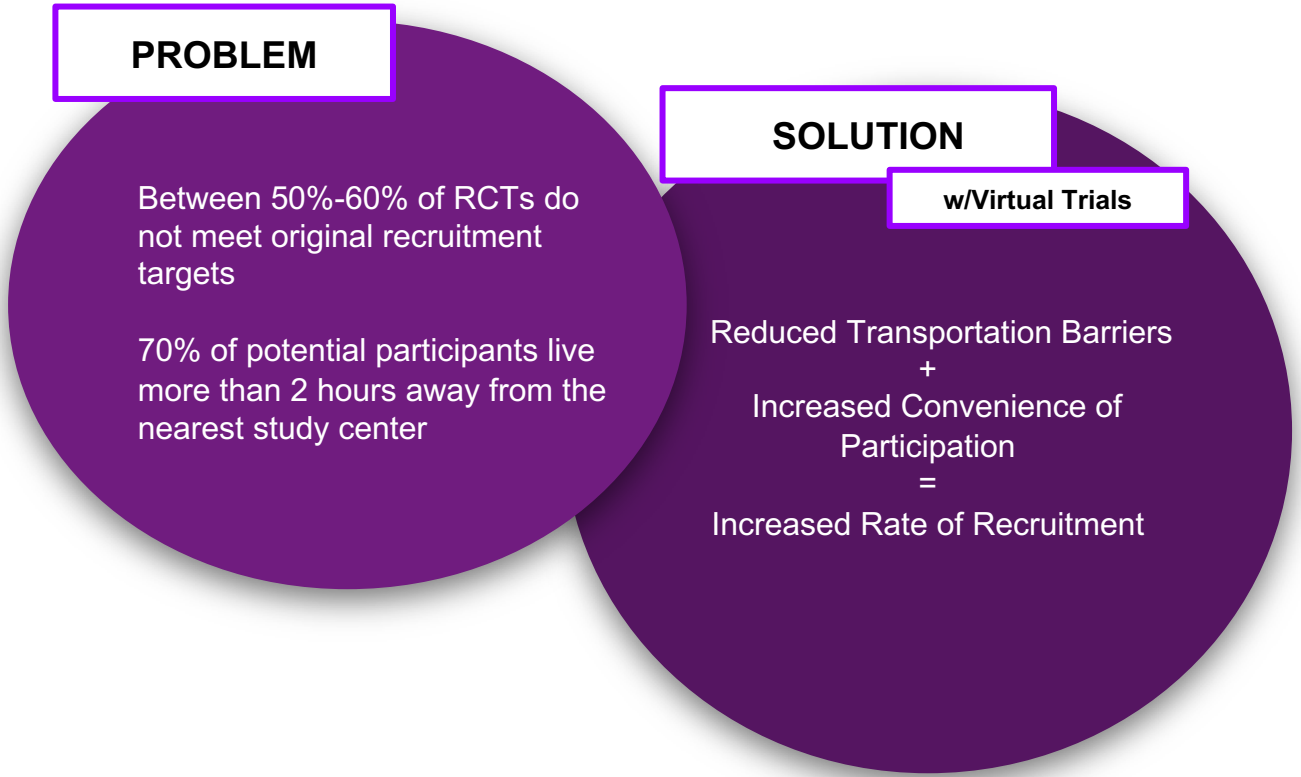
- Patient Engagement
- Recruitment
- Retention
- Compliance



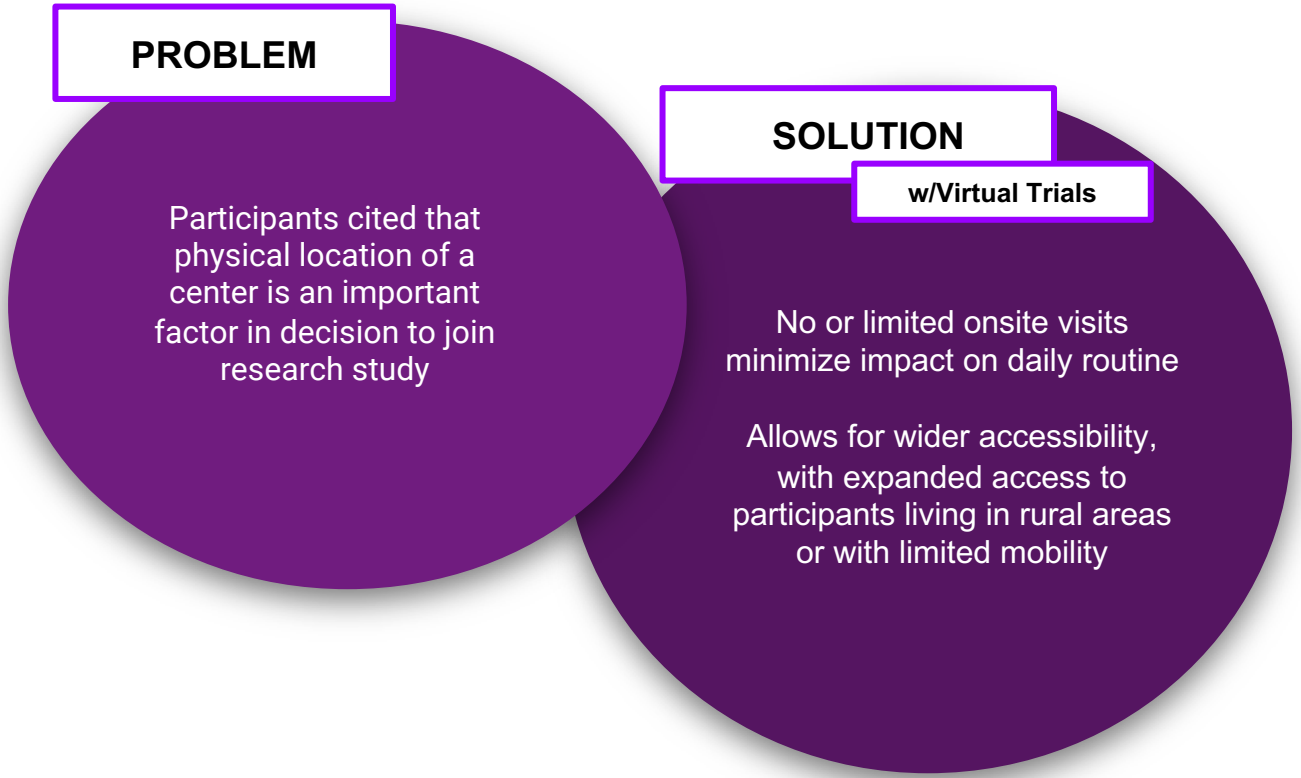
Current Barriers in Traditional Clinical Trials

1. Recruitment
2. Geographic Location/Transportation
3. Lack of Patient Centricity

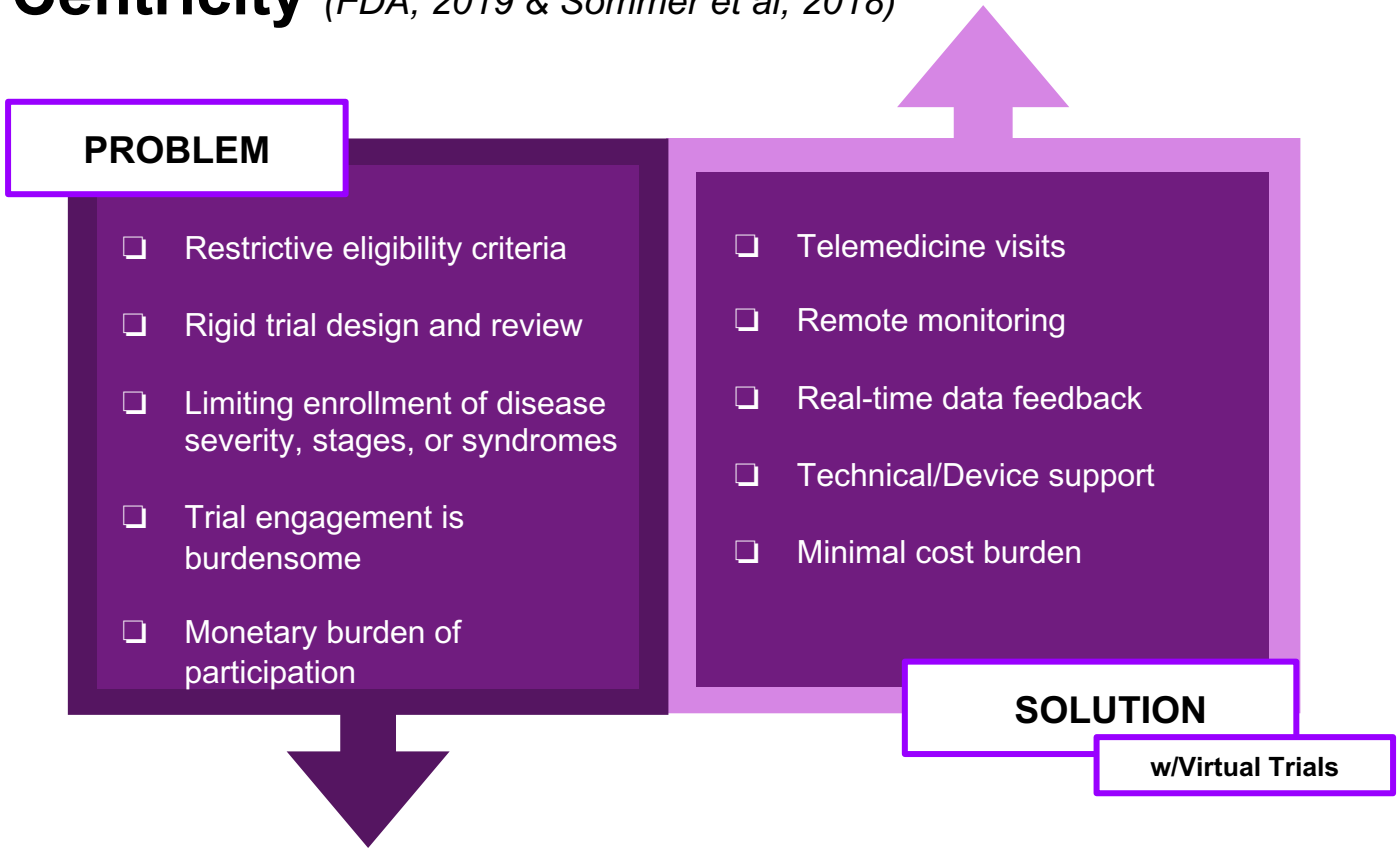
Recruitment *(Sommer et al, 2018)*



Geographic Barriers *(Sommer et al, 2018)*



Patient Centricity *(FDA, 2019 & Sommer et al, 2018)*



Decentralized Clinical Trials:

New challenges facing virtual trials

1

Protocol Design & Review

- Adapting Inclusion/Exclusion Criteria
- Methods & Assessments
- Clinically Meaningful Endpoints

2

Operational Logistics

- Capturing eConsent
- Technical Support with Device Usage
- Device Integrity
- Data Privacy

3

Recruitment & Retention

- Multi-step Recruitment Strategy (Facebook ads, etc)
- Study Procedure Compliance
- Caregiver Support
- Time Commitment

The key takeaway is that logistically, the goal behind driving virtual trials for investigators and businesses won't alter, but **we can control how we can inspire people to participate in research on terms that are equitable for them and create patient centric platforms** that do deliver on their promise.

(Dolgin, 2018)

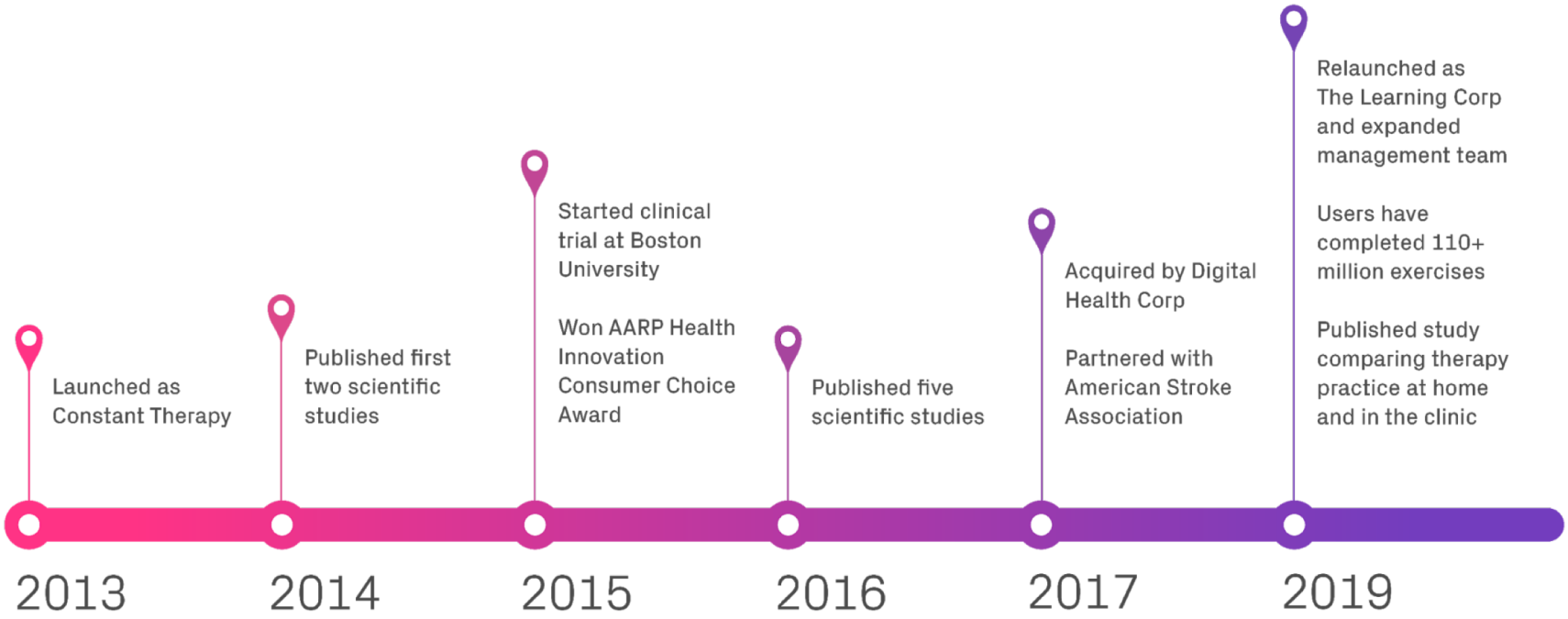
Decentralized Clinical Trials:

Tips for those involved in trial design

1. Select a CRO with expertise
2. Be transparent with CRO and vice versa
3. Establish an internal clinical team
4. Engage vendors early on in development process
5. Outline your milestones and budget

What is Constant Therapy?

The Learning Corp: brain health, for life



Who uses Constant Therapy?

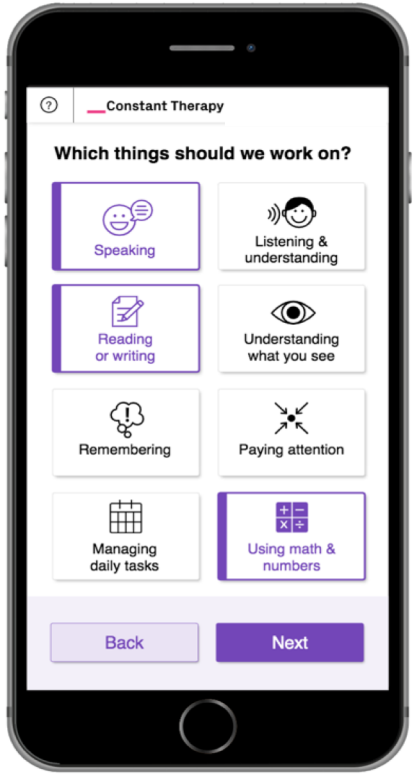
Patients recovering from stroke and traumatic brain injury, or living with speech, language or cognitive disorders.

Speech Language Pathologists (SLPs), professional caregivers and loved ones, who are helping these survivors rebuild every day skills like speech, language, cognition, memory, reading, attention and comprehension skills.

The companies who serve them: life sciences, payers/providers.

Constant Therapy

- **Mobile app:** 24/7 access to clinically-proven exercises that you can be used anytime, anywhere.
- **Evidence-based practice library:** More than 14 categories, 80+ exercises with up to 12 levels of difficulty.
- **Personalized care:** Uses AI engine and data analytics to deliver a personalized exercise program tailored to user goals and abilities.



NeuroPerformance Engine™ tailors the curriculum for each client

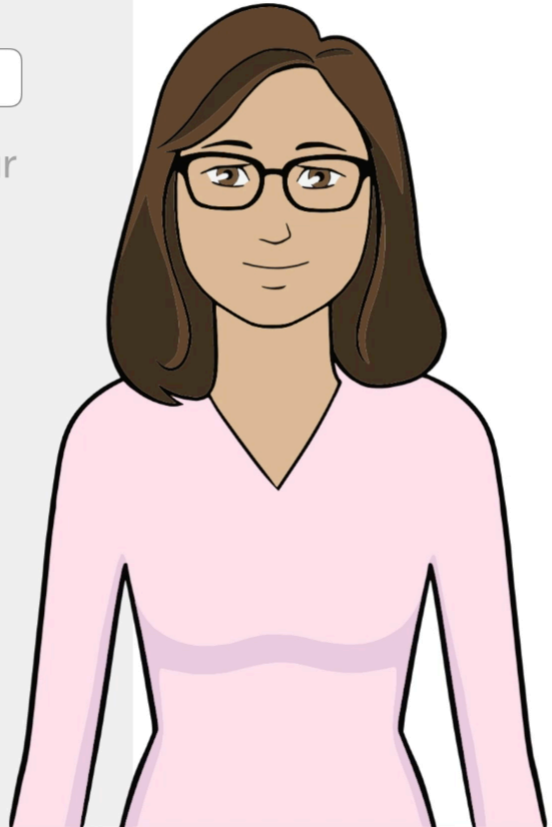
The foundation for our products, the patented NeuroPerformance Engine™, constantly monitors and analyzes client performance and progress.

It presents - and constantly adjusts - exercises based on clients' past performance data, and on the performance data of thousands of others with a similar condition.

You have practiced **2 days** this week

S	M	T	W	T	F	S

Let's try for at least four days this week. You're partway there!



Welcome back.

Let's do some therapy.

Start

Accuracy

Just right

The Learning Corp’s First Virtual Trial

GOAL: To Differentiate CT as a Digital Therapeutic

- There is a disparity between apps with research evidence and apps currently being used by consumers
- Despite emerge of curated app libraries for health apps *(Larsen et al, 2019)*, personal searches based on app description remains the common method for discovering apps
- Why does this pose an issue?

  Claims of effectiveness using scientific language might skew consumer's expectations of the therapy they are using

(Image from project Dialogue Report)

A parallel, virtual, randomized trial of CT-Research for speech, language, and cognitive intervention in stroke patients

Study Aims

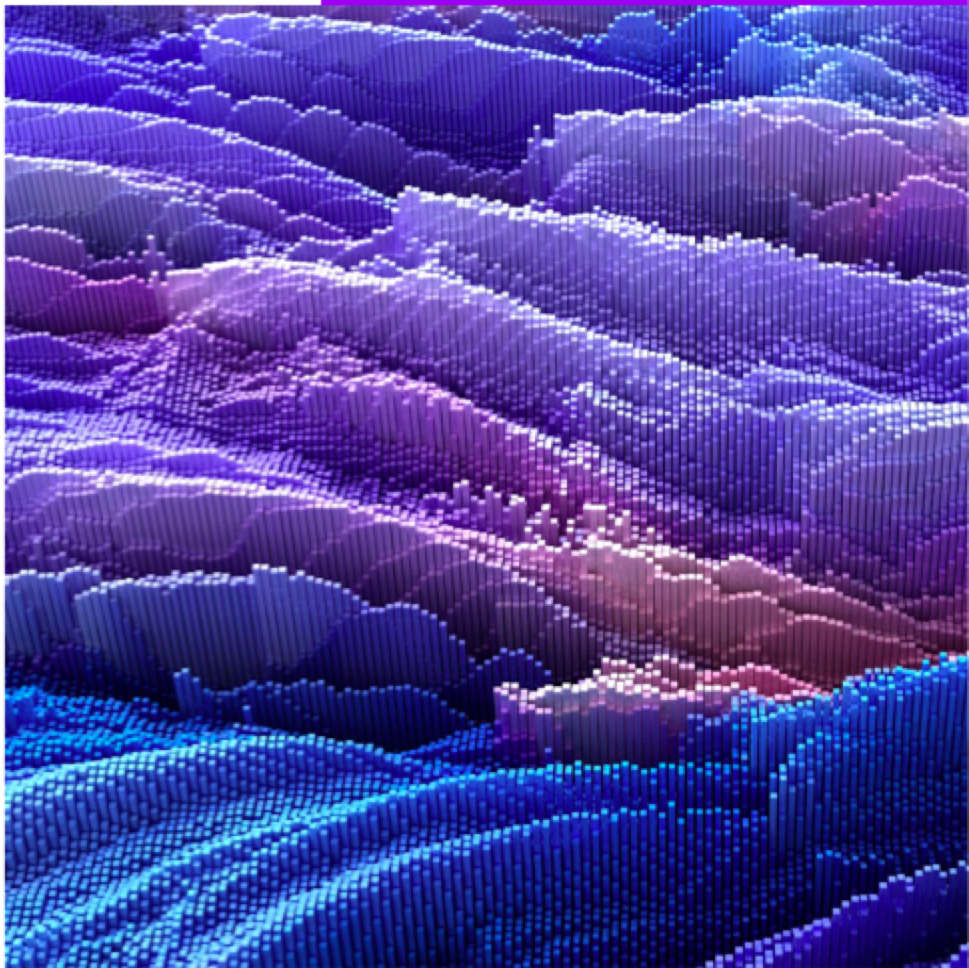
Primary Aim:

To evaluate the change in aphasia severity over time in experimental CT group vs a control group.

Secondary Aim:

Assess the feasibility of a remote assessment procedure and adherence to treatment in an experimental CT and a control group.

The Learning Corp



Study Design & Population

Population

30 people with post-stroke aphasia who had had a stroke at least 4 months prior and who were no longer getting skilled 1:1 SLP intervention

Study Design

Participants were recruited, screened, and assessed

After assessment, participants were placed into experimental or control group

Experimental: use of Constant Therapy app daily
Control: completion of workbook pages daily

Bi-weekly check-ins to check performance

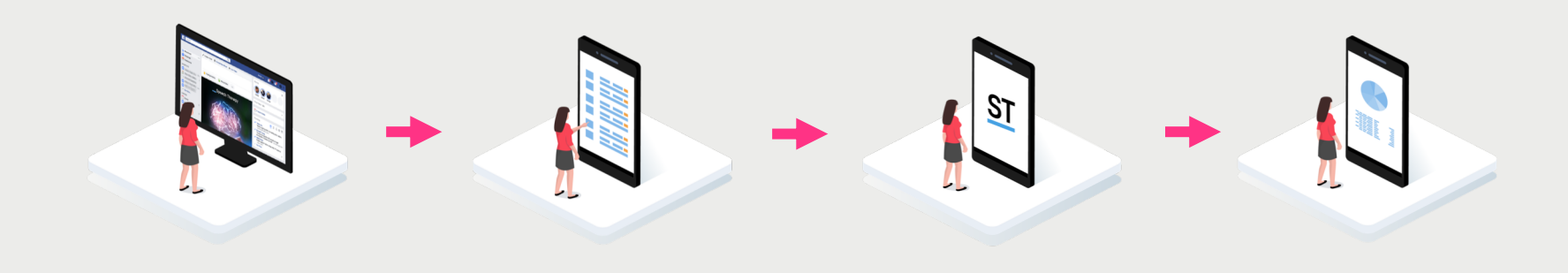
Post intervention remote assessment

Overview of Inclusion / Exclusion Criteria

We included participants who had a history of one stroke that resulted in speech and language deficits.

We excluded participants who had a history of multiple strokes, who had a stroke that did not result in language impairment, and participants who were still participating in skilled 1:1 SLP intervention.

Study on Virtual Speech Therapy



Recruitment

Facebook ads, Google ads, advocacy outreach, rehab centers, clinicians, email,
print collateral, website

Initial assessment

User receives kit at home and completes a language assessment with a clinician via video conference

Therapy

Therapy delivered via app to experimental group; clinician does biweekly virtual check-ins;
ST is used for 20 weeks total

Final assessment

Administered by clinician via videoconference

Findings from The Learning Corp’s decentralized trial

- Recruitment
- Scheduling and Communication
- Patient Engagement and Compliance
- Training of Technology
- Supply Management (shipping, storage, etc)

Summary

Wrapping Up

Decentralized trials have value	• Creates tailored protocol designs • Maximizes engagement from all study participants
DCTs have positive impact on recruitment	• Increases the rate of recruitment • Reaches out to heterogeneous populations • Widens access to rural populations
DCTs reduce participation burden	• Incorporates telemedicine visits • Allows remote monitoring/check-ins • Minimizes burden of cost
DCTs allow for real-time data collection	• Increases participant communication • Allows for study adherence and compliance monitoring

DCTs come with their own set of challenges, however, anticipating the road blocks is key to successful study design

Questions?

Get slides for today's presentation:

www.thelearningcorp.com/brainwire/asha-2019

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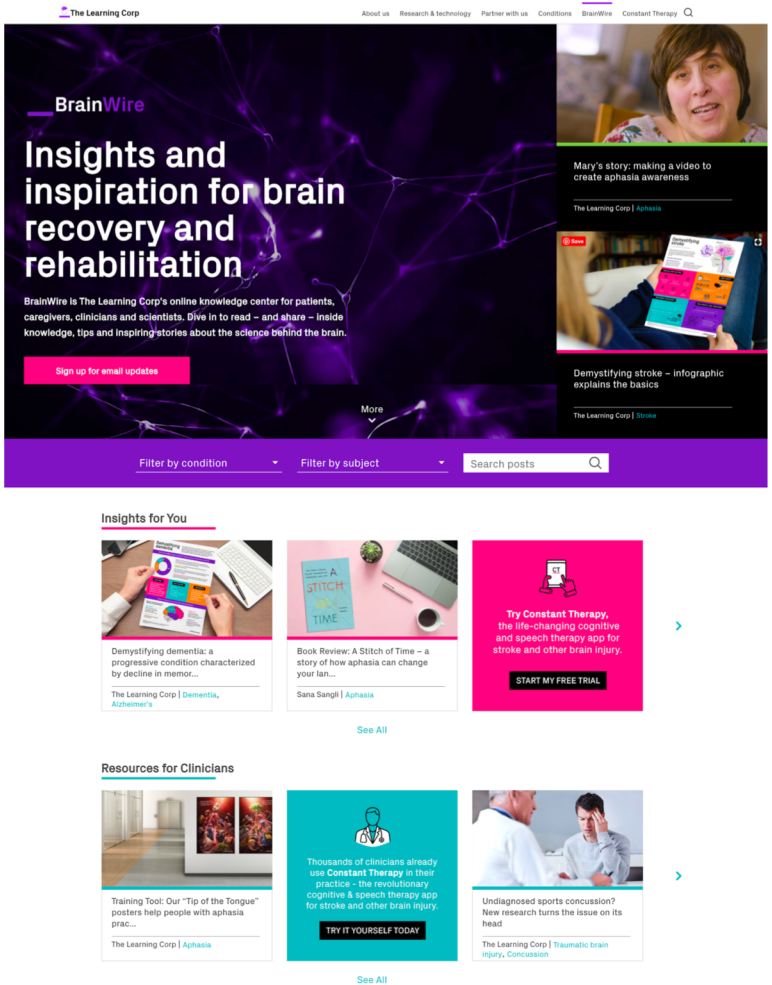

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